

Claims

- [c1] A nutritional supplement comprising:
at least one essential fatty acid selected from the group consisting of essential fatty acids, precursors thereof, derivatives thereof and mixtures thereof; and
at least one pharmaceutically acceptable iron compound;
wherein said nutritional supplement is provided in a capsule.
- [c2] The nutritional supplement of claim 1 wherein the capsule is a soft gelatin shell dosage form.
- [c3] The nutritional supplement of claim 1 wherein the essential fatty acid includes an essential fatty acid selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.
- [c4] The nutritional supplement of claim 1 wherein said pharmaceutically acceptable iron compound is incorporated into said nutritional supplement.
- [c5] The nutritional supplement of claim 1 further including at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings,

sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.

- [c6] A nutritional supplement comprising:
 - at least one essential fatty acid selected from the group consisting of essential fatty acids, precursors thereof, derivatives thereof and mixtures thereof; and
 - at least one pharmaceutically acceptable iron compound that is non-reactive with the at least one essential fatty acid;wherein said nutritional supplement is provided in a capsule.
- [c7] The nutritional supplement of claim 6 wherein the capsule is a soft gelatin shell dosage.
- [c8] The nutritional supplement of claim 6 wherein the iron compound is carbonyl iron.
- [c9] The nutritional supplement of claim 6 wherein the iron compound is an encapsulated iron compound.
- [c10] The nutritional supplement of claim 6 further including at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.

- [c11] The nutritional supplement of claim 6 wherein the essential fatty acid includes an essential fatty acid selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.
- [c12] The nutritional supplement of claim 6 wherein the essential fatty acid includes an omega-3 fatty acid.
- [c13] The nutritional supplement of claim 12 wherein the essential fatty acid is an omega-3 fatty acid.
- [c14] The nutritional supplement of claim 6 wherein the essential fatty acid comprises; about 10 mg to 1000 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 10 mg to 1000 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:0.01 to 10.
- [c15] The nutritional supplement of claim 6 wherein the essential fatty acid comprises; about 50 mg to 500 mg of a first fatty acid compound for each compound selected

from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 100 mg to 500 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:0.09 to 2.5.

[c16] The nutritional supplement of claim 6 wherein the essential fatty acid comprises; about 100 mg to 300 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 100 mg to 300 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:1 to 2.

[c17] The nutritional supplement of claim 6 wherein the at least one essential fatty acid includes at least one fatty acid selected from the group consisting of linolenic acid, linoleic acid, precursors thereof, derivatives thereof and

mixtures thereof.

- [c18] The nutritional supplement of claim 6 wherein the at least one essential fatty acid includes at least one essential fatty acid selected from the group consisting of arachidonic acid, docosahexanoic acid, eicosapentanoic acid, precursors thereof, derivatives thereof and mixtures thereof.
- [c19] The nutritional supplement of claim 6 further including folic acid, folate, a derivative or metabolite thereof.
- [c20] The nutritional supplement of claim 19 wherein the folic acid, folate, a derivative or metabolite thereof is less than about 5 mg.
- [c21] The nutritional supplement of claim 19 wherein the folic acid, folate, a derivative or metabolite thereof is from about 0.4 mg to about 5 mg.
- [c22] The nutritional supplement of claim 6 further including calcium.
- [c23] The nutritional supplement of claim 22 wherein the calcium is selected from the group consisting of calcium carbonate, dicalcium phosphate, tricalcium phosphate and mixtures thereof.
- [c24] The nutritional supplement of claim 6 further comprising

vitamin C.

- [c25] The nutritional supplement of claim 24, wherein said vitamin C is comprised of calcium ascorbate and calcium threonate.
- [c26] The nutritional supplement of claim 6 further comprising vitamin B6.
- [c27] The nutritional supplement of claim 6 wherein the at least one essential fatty acid and the at least one pharmaceutically acceptable iron compound are dissolved in a vehicle including a saturated oil.
- [c28] A nutritional supplement comprising:
 - about 150 mg of tribasic calcium phosphate;
 - about 300 mg of omega-3 essential fatty acid from fish oil;
 - about 27 mg of carbonyl iron;
 - about 30 mg of linolenic acid;
 - about 30 mg of linoleic acid;
 - about 30 mg of sunflower oil;
 - about 25 mg of vitamin C;
 - about 25 mg of vitamin B6;
 - about 1 mg of folic acid, folate, a derivative or metabolite thereof;
 - about 170 IU of vitamin D3; and

about 30 IU of vitamin E.

- [c29] The nutritional supplement of claim 28 wherein the capsule is a soft gelatin shell dosage form.
- [c30] A method of making a nutritional supplement for administration to said pregnant or lactating woman, the method comprising:
dispersing at least one essential fatty acid selected from the group consisting of essential fatty acids, precursors thereof, derivatives thereof and mixtures thereof with;
at least one pharmaceutically acceptable iron compound into a vehicle to form a viscous mixture; and
encapsulating the viscous mixture into a capsule.
- [c31] The nutritional supplement of claim 30 wherein the capsule is a soft gelatin shell dosage form.
- [c32] The method of claim 30 wherein the essential fatty acid includes an essential fatty acid selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.
- [c33] The method of claim 30 wherein the at least one essential fatty acid and the at least one pharmaceutically acceptable iron compound are dissolved in a vehicle including a saturated oil.

- [c34] The method of claim 30 wherein the nutritional supplement further includes at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.
- [c35] A method of making a nutritional supplement for administration to said pregnant or lactating woman, the method comprising:
ispersing at least one essential fatty acid selected from the group consisting of essential fatty acids, precursors thereof, derivatives thereof and mixtures thereof with at least one pharmaceutically acceptable iron compound that is non-reactive with the at least one essential fatty acid into a vehicle to form a viscous mixture; and encapsulating the viscous mixture into a soft gelatin shell dosage.
- [c36] The method of claim 35 wherein the capsule is a soft gelatin shell dosage form.
- [c37] The method of claim 35 wherein the iron compound is carbonyl iron.
- [c38] The method of claim 35 wherein the iron compound is

an encapsulated iron compound.

- [c39] The nutritional supplement of claim 35 further including at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.
- [c40] The method of claim 35 wherein the essential fatty acid includes an essential fatty acid selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.
- [c41] The method of claim 35 wherein the essential fatty acid includes an omega-3 fatty acid.
- [c42] The method of claim 35 wherein the essential fatty acid is an omega-3 fatty acid.
- [c43] The method of claim 35 wherein the essential fatty acid comprises; about 10 mg to 1000 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 10 mg to 1000 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid,

an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:0.01 to 10.

[c44] The method of claim 35 wherein the essential fatty acid comprises; about 50 mg to 500 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 50 mg to 500 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:0.09 to 2.5.

[c45] The method of claim 35 wherein the essential fatty acid comprises; about 100 mg to 300 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 100 mg to 300 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combi-

nation thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:1 to 2.

- [c46] The method of claim 35 wherein the at least one essential fatty acid includes at least one fatty acid selected from the group consisting of linolenic acid, linoleic acid, precursors thereof, derivatives thereof and mixtures thereof.
- [c47] The method of claim 35 wherein the at least one essential fatty acid includes at least one essential fatty acid selected from the group consisting of arachidonic acid, docosahexanoic acid, eicosapentanoic acid, precursors thereof, derivatives thereof and mixtures thereof.
- [c48] The method of claim 35 further including folic acid, folate, a derivative or metabolite thereof.
- [c49] The method of claim 48 wherein the folic acid, folate, a derivative or metabolite thereof is less than about 5 mg.
- [c50] The method of claim 48 wherein the folic acid, folate, a derivative or metabolite thereof is from about 0.4 mg to about 5 g.
- [c51] The method of claim 35 further including calcium.
- [c52] The method of claim 51 wherein the calcium is selected

from the group consisting of dicalcium phosphate and tricalcium phosphate.

[c53] The method of claim 35, wherein the nutritional supplement further comprises vitamin C.

[c54] The method of claim 53, wherein the vitamin C is selected from the group consisting of calcium ascorbate, calcium threonate and mixtures thereof.

[c55] The method of claim 35, wherein the nutritional supplement further comprises vitamin B6.

[c56] The method of claim 35 wherein the at least one essential fatty acid and the at least one pharmaceutically acceptable iron compound are dissolved in a vehicle including a saturated oil.

[c57] A method of providing nutritional support to a pregnant or lactating woman and her child, which comprises administering a nutritional supplement for administration to said pregnant or lactating woman, the nutritional supplement comprising:

about 150 mg of tribasic calcium phosphate;

about 300 mg of omega-3 essential fatty acid from fish oil;

about 27 mg of carbonyl iron;

about 30 mg of linolenic acid;

about 30 mg of linoleic acid;
about 30 mg of sunflower oil;
about 25 mg of vitamin C;
about 25 mg of vitamin B6;
about 1 mg of folic acid, folate, a derivative or metabolite thereof;
about 170 IU of vitamin D3; and
about 30 IU of vitamin E.

[c58] The nutritional supplement of claim 57 wherein the capsule is a soft gelatin shell dosage form.

[c59] A method for administering a nutritional supplement, the method comprising:
orally administering to a pregnant or lactating woman a capsule comprising;
at least one essential fatty acid selected from the group consisting of at least one essential fatty acid, at least one essential fatty acid precursor, at least one derivative of an essential fatty acid and mixtures thereof; and
at least one pharmaceutically acceptable iron compound;
wherein said nutritional supplement is provided in a soft gelatin shell dosage.

[c60] The method of claim 59 wherein the capsule is a soft gelatin shell dosage form.

- [c61] The method of claim 59 wherein the essential fatty acid is selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.
- [c62] The method of claim 59 wherein the at least one essential fatty acid and the at least one pharmaceutically acceptable iron compound are dissolved in a vehicle including a saturated oil.
- [c63] The method of claim 59 wherein the nutritional supplement further includes at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.
- [c64] A method for administering a nutritional supplement, the method comprising:
orally administering to a pregnant or lactating woman a capsule comprising;
at least one essential fatty acid selected from the group consisting of at least one essential fatty acid, at least one essential fatty acid precursor, at least one derivative of an essential fatty acid and mixtures thereof; and
at least one pharmaceutically acceptable iron compound that is non-reactive with the at least one essential fatty

acid;

wherein said nutritional supplement is provided in a soft gelatin shell dosage.

- [c65] The method of claim 64 wherein the capsule is a soft gelatin shell dosage form.
- [c66] The method of claim 64 wherein the iron compound is carbonyl iron.
- [c67] The method of claim 64 wherein the iron compound is an encapsulated iron compound.
- [c68] The method of claim 64 wherein the nutritional supplement further includes at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.
- [c69] The method of claim 64 wherein the essential fatty acid is selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.
- [c70] The method of claim 64 wherein the essential fatty acid includes an omega-3 fatty acid.
- [c71] The method of claim 64 wherein the essential fatty acid

is an omega-3 fatty acid.

[c72] The method of claim 64 wherein the essential fatty acid comprises; about 10 mg to 1000 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 10 mg to 1000 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:0.01 to 10.

[c73] The method of claim 64 wherein the essential fatty acid comprises; about 50 mg to 500 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 50 mg to 500 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:0.09 to 2.5.

[c74] The method of claim 64 wherein the essential fatty acid comprises; about 100 mg to 300 mg of a first fatty acid compound for each compound selected from the group consisting of a linoleic acid compound, a linolenic acid compound, a derivative thereof and a combination thereof; about 100 mg to 300 mg of a second fatty acid compound selected from the group consisting of a docosahexaenoic acid compound, an omega-3 fatty acid, an omega-2 fatty acid, a derivative thereof and a combination thereof; and wherein the weight ratio of said first fatty acid compound to said second fatty acid compound is about 1:1 to 2.

[c75] The method of claim 64 wherein the at least one essential fatty acid includes at least one fatty acid selected from the group consisting of linolenic acid, linoleic acid, precursors thereof, derivatives thereof and mixtures thereof.

[c76] The method of claim 64 wherein the at least one essential fatty acid includes at least one essential fatty acid selected from the group consisting of arachidonic acid, docosahexanoic acid, eicosapentanoic acid, precursors thereof, derivatives thereof and mixtures thereof.

[c77] The method of claim 64 further including folic acid, fo-

late, a derivative or metabolite thereof.

[c78] The method of claim 77 wherein the folic acid, folate, a derivative or metabolite thereof is less than about 5 mg.

[c79] The method of claim 77 wherein the folic acid, folate, a derivative or metabolite thereof is from about 0.4 mg to about 5 mg.

[c80] The method of claim 64 further including calcium.

[c81] The method of claim 80 wherein the calcium is selected from the group consisting of calcium carbonate, dicalcium phosphate, tricalcium phosphate and mixtures thereof.

[c82] The method of claim 64, further comprising vitamin C.

[c83] The method of claim 82, wherein said vitamin C is comprised of calcium ascorbate and calcium threonate.

[c84] The method of claim 64, further comprising vitamin B6.

[c85] The method of claim 64 wherein the at least one essential fatty acid and the at least one pharmaceutically acceptable iron compound are dissolved in a vehicle including a saturated oil.

[c86] A method for administering a nutritional supplement, the method comprising:

orally administering to a pregnant or lactating woman a capsule comprising;
about 150 mg of tribasic calcium phosphate;
about 300 mg of omega-3 essential fatty acid from fish oil;
about 27 mg of carbonyl iron;
about 30 mg of linolenic acid;
about 30 mg of linoleic acid;
about 30 mg of sunflower oil;
about 25 mg of vitamin C;
about 25 mg of vitamin B6;
about 1 mg of folic acid, folate, a derivative or metabolite thereof;
about 170 IU of vitamin D3; and
about 30 IU of vitamin E.

[c87] The method of claim 86 wherein the capsule is a soft gelatin shell dosage form.

[c88] The method of claim 86 wherein the nutritional supplement further includes at least one additive selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, fragrances, aromatics, edible oils, polymers, buffers, adsorbents and mixtures thereof.